FINDING OF NO SIGNIFICANT IMPACT

for

Menadione Nicotinamide Bisulfite
for Use in Poultry Diets

FAP 2228

Vanetta, S.P.A.
Milan, Italy

FOR PUBLIC DISPLAY

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The Center for Veterinary Medicine has carefully considered the potential environmental impact of this action and has concluded that this action will not have a significant effect on the quality of the human environment and that an environmental impact statement therefore will not be prepared.

Vanetta S.P.A. has submitted a Food Additive Petition for the marketing of menadione nicotinamide bisulfite (MNB) as a source of vitamin K activity and supplemental niacin in poultry diets at a level up to 4 grams per ton on a complete feed basis. The product is manufactured by Vanetta S.P.A. industrial plant located in Comune Di Marcianise, Italy.

The sponsor has submitted an environmental assessment (EA; dated June 27, 1994), to provide the information required under 21 CFR 25.31a(b)(5), for the manufacture and use of the product.

The sponsor provides a certificate of compliance issued by the Mayor ("Sindaco") of the Commune of Marcianise, Province of Caserta. The sponsor states that the office of the Mayor is charged with ensuring that companies operating within the province are in compliance with all Italian laws, which include, but are not limited to, all environmental and occupational 'matters'.

To address environmental issues related to the use of the product in animals, the sponsor cites the November 1990 environmental assessment (EA) and Finding of No Significant Impact (FONSI) that was prepared by the Center to support a notice concerning the regulatory status of certain vitamin K substances (VKAS) (55 FR 50777). The sponsor adequately demonstrates that the information in the EA is applicable to the menadione and bisulfite portions of MNB. The Center's EA discusses the environmental fate and effects of VKAS and provides information to demonstrate that menadione is either metabolized by soil and water microorganisms, decomposed in sunlight, or taken up by bacteria. The EA concludes that given the low exposures that may occur in animal wastes and the degradation of VKAS in the environment, the potential for adverse effects on exposed organisms in the environment appears to be low. Although this EA does not provide information on the nicotinamide moiety of MNB, this naturally occurring vitamin (niacin) is also expected to be degraded or utilized in the environment. Nicotinamide is the amine of nicotinic acid, is synthesized by plants and most animals from other precursors, primarily tryptophan, and is required by microorganisms as a component of NAD. This information demonstrates that the use of the product can reasonably be expected not to alter significantly the concentration and distribution of the product or metabolites in the environment.

We have reviewed the EA and determined that it is adequate to conclude that the manufacture and use of the product is not expected to have a significant impact on the human environment.

12/8/94 — Date
Preparer, Environmental Sciences Staff, HFV-152

12/8/94 — Date
Primary Action Officer, HFV-226

12/8/94 — Date
Roger A. Jones for CEE III
Chief, Environmental Sciences Staff, HFV-152

Attachment: Environmental Assessment, June 27, 1994.